

## § 866.5100

of liver tissue) and chronic active hepatitis (inflammation of the liver).

(b) *Classification.* Class II (performance standards).

### § 866.5100 Antinuclear antibody immunological test system.

(a) *Identification.* An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum, other body fluids, and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins). The measurements aid in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which antibodies attack the victim's own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjogren's syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

(b) *Classification.* Class II (performance standards).

### § 866.5110 Antiparietal antibody immunological test system.

(a) *Identification.* An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in serum and other body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin B<sub>12</sub> to be absorbed by the body. The measurements aid in the diagnosis of vitamin B<sub>12</sub> deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

(b) *Classification.* Class II (performance standards).

### § 866.5120 Antismooth muscle antibody immunological test system.

(a) *Identification.* An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by

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immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).

(b) *Classification.* Class II (performance standards).

### § 866.5130 Alpha-1-antitrypsin immunological test system.

(a) *Identification.* An alpha-1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-antitrypsin (a plasma protein) in serum, other body fluids, and tissues. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

(b) *Classification.* Class II (performance standards).

### § 866.5150 Bence-Jones proteins immunological test system.

(a) *Identification.* A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and plasma. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in urine and plasma, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by

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spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

(b) *Classification*. Class II (performance standards).

### § 866.5160 *Beta-globulin immunological test system.*

(a) *Identification*. A *beta*-globulin immunological test system is a device that consists of reagents used to measure by immunochemical techniques *beta* globulins (serum protein) in serum and other body fluids. *Beta*-globulin proteins include *beta*-lipoprotein, transferrin, glycoproteins, and complement, and are rarely associated with specific pathologic disorders.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

### § 866.5170 *Breast milk immunological test system.*

(a) *Identification*. A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]

### § 866.5180 *Fecal calprotectin immunological test system.*

(a) *Identification*. A fecal calprotectin immunological test system is an *in vitro* diagnostic device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended for *in vitro* diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn's disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.

(b) *Classification*. Class II (special controls). The special control for these devices is FDA's guidance document entitled "Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems." For the availability of this guidance document, see § 866.1(e).

[71 FR 42598, July 27, 2006]

### § 866.5200 *Carbonic anhydrase B and C immunological test system.*

(a) *Identification*. A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques specific carbonic anhydrase protein molecules in serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

### § 866.5210 *Ceruloplasmin immunological test system.*

(a) *Identification*. A ceruloplasmin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, other body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

(b) *Classification*. Class II (performance standards).

### § 866.5220 *Cohn fraction II immunological test system.*

(a) *Identification*. A Cohn fraction II immunological test system is a device that consists of the reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominantly of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques.